

## UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office

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APPLICATION NO. FILING DATE JAHODA FIRST NAMED INVENTOR A ATTORNEY DOCKET NO.

HM12/0425

Please find below and/or attached an Office communication concerning this application or

DAVID A JACKSON KLAUBER & JACKSON 411 HACKENSACK AVENUE 4TH FLOOR HACKENSACK NJ 07601

proceeding.

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DATE MAILED:

**Commissioner of Patents and Trademarks** 

Application No.   Application	<u> </u>		***					
### Examiner   Group Art Unit   CuBMM   Cu D    ### Communication appears on the cover sheet beneath the correspondence address—  P ri d for Response  A SHORTENED STATUTORY PERIOD FOR RESPONSE IS SET TO EXPIRE   MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be a railished under the provisions of 37 CFR 1.136(a). In no event, however, may a response be timely filled after SIX (8) MONTHS from the mailing date of this communication.  - If No period for response specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period for response is specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period for response is specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period for response is specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period or response specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period or response specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period or response specified above, such period shall, by default, expire SIX (8) MONTHS from the mailing date of this communication.  - If No period or response specified is some or response with the practice under Expired for the period or specified in the period of the specified in the period of the pe		Application No.						
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U. S. Patent and Trademark Office PTO-326 (Rev. 3-97) Application/Control Number: 09/463174

Art Unit: 1617

## 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 11-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim dermal sheath tissue, which is a product of nature.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 "comprised by" is indefinite; the preposition is grammatically improper. "can" is vague; under what conditions? It is unclear whether what follows "can" is definitely claimed.

In claims 6, 16, 24, 26 "suitable" and "suitably" are vague; the terms are subjective.

In claim 7 "functionally inserted" is indefinite; the adverb is unrelated to the verb.

In claims 9 and 10 "similar nature" and "different nature" are vague; they are subjective.

In claim 11 "arranged" is vague; what steps are taken?

In claims 12 and 14 "operationally linked" is vague; the adverb is unrelated to the verb.

In claim 15 "can be placed" is vague; under what condition?

In claims 17 and 18 "formulated" is vague; what formula?

In claims 19 and 20 "include" and "includes" are vague; the terms are non-limiting.

In claims 21, 22, 25, and 31 "adapted" is vague; what steps are taken?

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In claim 22 "so" is vague; what follows is not necessitated by what precedes the term.

In claims 23, 26, 34 and 36 "associated" is vague; it is subjective.

Claim 23 appears to be a statement rather than a description of the invention. Is "which" intended after "appliance" in line 1?

In claim 24 "accomodate" and "have the capacity" are vague; what follows is not definitely claimed.

In claim 26 "embedded" appears to be superfluous to "incorporated".

In claim 28 "highly complex" is subjective.

In claim 29 "extracellular matrix products" is vague and indefinite. What cells? Does the matrix produce a product?

In claims 34 and 36 "closely" is subjective.

In claim 34 "typically" is vague; what follows is not definitely claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by WO93/22430 (WO '430) and applicants' disclosure, page 10 line 6.

WO '430 teaches a vector with sites for insertion for insertion of genes (abstract).

Applicants further disclose the commercially available Introgen vector which possesses such sites.

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Claims 6 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. On page 22 lines 1-9 and on page 28 line 27-page 29 line 14, applicants transfection of dermal sheath tissue with a vector containing a gene, namely the Invitrogen vector containing the eGFP gene. Applicants do not disclose transfection with the Invitrogen vector without the eGFP gene and later insertion of the gene into the vector after transfection (an apparently senseless procedure).

Claims 16-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Nowhere in the specification does applicant disclose the how to make the claimed compositions containing dermal sheath tissue and the claimed carriers..

Claim 24-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Nowhere in the specification do applicants disclose how to make dermal sheath tissue altered so as to make it more succeptable to transfection. (Applicants do disclose how to maketransfected dermal sheath tissue.)

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Claims 25-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Nowhere in the specification do applicants disclose how to make the claimed wound healing system, nor do they disclose how to make the particular matrices containing a gene therapy vehicle.

No claims allowed.